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UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office

APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 708,918	11 08 2000	Julia J. Dibner	NVI-50091	2670

321 7590 03 06 2003

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16TH FLOOR  
ST LOUIS, MO 63102

EXAMINER

DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED 03 06 2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/708,918

Applicant(s)

Dibner et al

Examiner

Patricia A. Duffy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Dec 18, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 55-75 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 55-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s).
- 4) ☐ Interview Summary (PTO-413) Paper No(s).
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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*Response to Amendment*

1. The amendment and response filed 12-08-02 has been entered into the record. Claims 55-75 are under examination, all other claims having been canceled. The amendments to the specification at page 21, line 1 and page 21, line 26 could not be entered because the recited page and line numbers does not correspond to textual information at the indicated placement.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

*Rejections Withdrawn*

3. The rejection of claims 1-10 and 25-27 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn based on Applicants amendments.
4. The rejection of claims 1-6, 8-10, 25 and 27 under 35 U.S.C. 102(b) as being anticipated by Evans et al (WO 96/40233, published 12 December 1999) is withdrawn across the new claims in view of the now claimed limitation that recites that the preparation must be "sterile".
5. The rejection of claims 1-10, 25 and 27 are under 35 U.S.C. 103(a) as being unpatentable over Evans et al (WO 96/40233; published 12 December 1999) in view of MacDonald et al (U.S. Patent No. 5,055,292, issued October 8, 1991) is withdrawn across the new claims in view of the now claimed limitation that recites that the preparation must be "sterile".

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6. The rejection of claims 1-10 and 25-27 under 35 U.S.C. 103(a) as being unpatentable over Evans et al (WO 96/40233; published 12 December 1999) in view of MacDonald et al (U.S. Patent No. 5,055,292, issued October 8, 1991) as applied to claims 1-10, 25 and 27 and further in view of Rolinski et al (Medycyna Weterynaryjna, 44(8):abstract 1988) or Thaxton (U.S. Patent 5,311,841; issued may 17, 1994) is withdrawn across the new claims in view of the now claimed limitation that recites that the preparation must be "sterile".

*Rejections Maintained*

7. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. (see non-entry of amendment recited above).

*New Rejections Based on Amendment*

*Claim Rejections - 35 U.S.C. § 112*

8. Claims 55-75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims have been amended to recite that the preparation of "live sporocysts" is "sterile". The specification does not support this recitation. The specification teaches sanitization of the preparation by conventional means (sodium hypochlorite) to render the preparation "substantially free" of bacteria, fungi and viruses. See in particular page 15, first full paragraph and page 16, third full paragraph. These passages specifically teach

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that such sanitization methods "Any method that results in the destruction of microbial contaminants, but does not significantly decrease the viability of the coccidial parasites can be used." Therefore, *the preparation can not be sterile*, because such provides for killed and not live sporocysts as is claimed. The specification does not teach nor does the specification contemplate that any preparation comprising live sporocysts as "sterile". The specification washes with sterile pharmaceutical agents, but such washing with sterile pharmaceutical agents does not provide for conception of a sterile preparation of an "infectious agent", the sporocyst. This provides for a fundamental contradiction of the accepted meaning of "sterile" and the specification does not provide for conception of a sterile preparation as claimed.

9. Claims 55-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants now claim a sterile preparation comprising live sporocysts. Sterile is defined in the pharmaceutical arts as "free from living organisms" (see Webster's Ninth New Collegiate Dictionary (page 1156). By definition, a preparation can not be sterile and contain a live infectious agent (live sporocysts) at the same time. As such, the basic fundamental contradiction introduced by Applicants amendments renders the scope, breadth and intent of the claims uninterpretable by the skilled artisan.

#### *Status of Claims*

10. All claims stand rejected.

#### *Conclusion*

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11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

12. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.

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March 4, 2003

*Patricia A. Duffy*  
Patricia A. Duffy, Ph.D.  
Primary Examiner  
Group 1600